

**REMARKS**

Claims 1-12 are pending in this application, with claims 23-32 standing withdrawn. Claims 1-12 stand rejected for the reasons indicated in the Office Action. In response, claim 1 has been amended, claims 23-32 have been canceled, and new claims 33-62 have been added. No new matter is added by these amendments. Entry of these amendments is hereby requested.

**With Respect to Claims 23-32, Paragraph 2 of the Outstanding Office Action:**

Claims 23-32 been canceled.

**With Respect to the Rejections under 35 U.S.C. §102(b), Paragraph 6 of the Outstanding Office Action:**

Claims 1, 2, 4, 7 and 11 stand rejected under 35 U.S.C. §102(b) as being anticipated by Loessner et al. for the reasons discussed in paragraph 7 of the Office Action. Claim 1 has been amended to incorporate the limitation of claim 6 and claim 6 has been canceled. As indicated below, claim 1 is now believed to be patentable. Claims 2, 4, 7 and 11 depend on claim 1. Therefore, the Applicant requests that the rejection of claims 1, 2, 4, 7 and 11 under 35 U.S.C. §102(b) be withdrawn.

**With Respect to the Rejections under 35 U.S.C. §103(a), Paragraphs 8 and 9 of the Outstanding Office Action:**

Claims 9, 10 and 12 stand rejected under 35 U.S.C. §103(a) as being obvious over United States Patent 5,736,351 to Miller et al. in view of Contag et al. and further in view of United States Patent 5,814,331 to Holen, for the reasons indicated in paragraphs 8 and 9 of the Office Action. Further, claims 1-8, 11 and 12 stand rejected under 35 U.S.C. §103(a) as being obvious over United States Patent 5,736,351 to Miller in view of Billard et al. for the reasons indicated in paragraph 9 of the Office Action.

Claim 1 has been amended to incorporate the limitation of claim 6, and claim 6 has been canceled. Claims 2-5, and 7-12 have not been amended and depend on claim 1. New claims 33 through 62 have been added as follows. Claim 33 is claim 1 incorporating the

limitation of claim 3. Claims 34-42 contain exactly the limitations of claims 2, 4-9 and 11-12, now dependent on claim 33. Claim 43 is claim 1 incorporating the limitation of claim 9. Claims 44-52 contain exactly the limitations of claims 2-9 and 11-12, now dependent on claim 43. Claim 53 is claim 1 incorporating the limitation of claim 12. Claims 54-6 contain exactly the limitations of claims 2-10, now dependent on claim 53. No new matter is added by these amendments.

Of the pending claims, claims 1, 33, 43 and 53 are independent. All of these independent claims contain the following common limitations, among others (emphasis added):

A method for evaluating whether an implantable material will allow modified living bacteria to pass through the implantable material or around the implantable material or into the implantable material comprising:

a) providing living bacteria which are modified to produce a first detectable signal;

b) placing the modified living bacteria on a first side of the implantable material being evaluated; and

c) detecting whether the first signal is present on a second side of the implantable material or within the implantable material;

where absence of the first signal on the second side of the implantable material or within the implantable material indicates that the modified living bacteria have not passed through or around the implantable material and where presence of the first signal on the second side of the implantable material or within the implantable material indicates that the modified living bacteria have passed through or around the implantable material; [and]

where the implantable material is non-living.

With respect to United States Patent 5,736,351 to Miller et al., the United States Patent and Trademark Office stated in paragraph 9 of the Office Action:

The claims are drawn to a method for evaluating whether an implantable material will allow modified living bacteria to pass through the implantable material or around the implantable material or into the implantable material comprising: a) providing modified bacteria to produce a first detectable signal; b) placing the modified bacteria on the first side of the implantable material;

and c) detecting whether the first signal is present on the implantable material where the implantable material is non-living. The dependant [sic] claims are drawn to the signal being in the visible spectrum and the bacteria incorporating functional luciferase and a second green fluorescent protein detectable signal.

This is not true. The section from the Office Action appears to have been lifted directly from an Office Action dated January 14, 2005 for co-pending United States Patent Application 10/356,245 and does not describe the pending claim set for the present application.

Next, the Patent and Trademark Office stated that "Miller et al., teach determining whether signal is present on the material," apparently referring to a limitation in the claim set pending in the '245 application, not the present application. As indicated above, all pending claims in the present claim set includes the limitation "detecting whether the first signal is present on a second side of the implantable material or within the implantable material . . . ." The Patent and Trademark Office has not cited any support for an assertion that Miller et al. teach determining whether signal is present on the material, (as in the '245 application), or on a second side of the implantable material or within the implantable material (as in the present claim set).

United States Patent 5,736,351 to Miller et al. discloses a series of methods, and some devices to be used with the methods, for determining contamination on certain types of surfaces. The methods are summarized in the '351 Patent as follows (emphasis):

. . . One embodiment of the present invention is a method for determining the total microbial contamination comprising the steps of:

- a) collecting a surface sample with a collection means and
- b) agitating said collection apparatus means with a fluid phase to dislodge the surface contaminants into a fluid phase, said fluid phase [sic] the becoming the collectate and
- c) placing an aliquot of said collectate into a disposable test device, and
- d) adding a washing/lysing reagent that lyses any somatic cells present in the aliquot; and

e) applying a positive pressure to the top of the disposable test device or negative pressure to the bottom of the disposable test device to eliminate the liquid phase containing free ATP and any chemical inhibitors as well as concentrating the bacteria at the interface, and

f) adding a bacterial lysing reagent that perforates the bacterial cell walls allowing the release of microbial ATP, and

g) adding ATP free luciferin and luciferase reagent, and

**h) determining the amount of ATP present by measuring the light emitted through translucent sides of said disposable test device. [col. 4, lines 16-29]**

The invention further concerns a detection method in which the presence and quantity of specific microbes on a surface can be detected in a time frame less than one hour, said method comprising the steps of:

**a) Providing a clean disposable test device comprising an open top, translucent sides and a porous filter attached to the bottom side,**

b) Adding an aliquot of collectate, said collectate being that described as above,

c) Adding an appropriate wash solution comprised of detergent, or buffered salts or a combination thereof,

d) Applying positive pressure to the top of the disposable test device, or negative pressure to the bottom of the disposable test device to remove fluid from the device and deposit microbes or target analytes directly or indirectly onto the surface of the porous filter,

e) Adding a specific labeled antibody directed against the specific microbes to be detected and incubating for an appropriate period of time,

f) Applying positive pressure to the top of the disposable test device, or negative pressure to the bottom of the disposable test device to remove fluid containing unreacted enzyme labeled antibody from the device,

g) Adding an appropriate wash solution comprised of detergent and buffered salts,

h) Applying positive pressure to the top of the disposable test device, or negative pressure to the bottom of the disposable test device to further remove fluid containing unreacted labeled antibody from the device,

**i) Adding a chemiluminescent substrate and determining the amount of light emitted by the chemiluminescent substrate using a photometer that accommodates the disposable test device in a manner which allows its precise positioning with respect to the surface of the photosensor and which precludes any possible loss of the final reaction mixture during and after the measurement cycle.**  
[col. 5, lines 24-67]

As far as the Applicant can determine, every method disclosed in the '351 Patent requires that a sample from the surface with the potential contamination be collected and placed into a specialized device for treatment. As can be appreciated from the bolded sections above, and from the rest of the disclosure in the '351 Patent, any signal detected from the sample is detected in the specialized device, **not on a second side of the implantable material or within the implantable material tested itself** (the "surface" as used in the '351 Patent).

The Patent and Trademark Office has not, in fact, cited a single passage in the '351 Patent which teaches or suggests:

- 1) detecting whether the first signal is present on a second side of the implantable material or within the implantable material;
- 2) where absence of the first signal on the second side of the implantable material or within the implantable material indicates that the modified living bacteria have not passed through or around the implantable material and where presence of the first signal on the second side of the implantable material or within the implantable material as is recited in each independent pending claim.

Further, the Patent and Trademark Office has not cited any passage in Contag et al. further in view of United States Patent 5,814,331, or in Billard et al. to make up this deficiency. Hence, a *prima facie* case of obviousness has not been established as no combined disclosure in the cited references either explicitly or inherently teaches or suggests the subject matter of present independent claims 1, 33, 43 and 53, previously pending claims 3, 6, 9 and 12. Pending claims 2-5, 7-12 and 33-62 dependent on claims 1, 33, 43 and 53 as indicated

above. Therefore, the Applicant request that the rejections under 35 U.S.C. §103(a) be withdrawn.

**With Respect to the Double Patenting Rejection, Paragraph 11 of the Office Action:**

Claims 1-8 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-10 of co-pending application 10/356,245 for the reasons indicated in paragraph 11 of the Office Action. The '981 application is a divisional application of the present patent application. Claims 1-10 of the '245 application were originally claims 13-22 of the present application. The '245 application was filed after a restriction requirement in the present application determined that claims 13-22 were patentably distinct. Hence, this obviousness-type double patenting rejection is barred by the United States Patent and Trademark Office's own action under MPEP 804 and 37 C.F.R. 121, and withdrawal is hereby requested.

**CONCLUSION**

The Applicants believe that all pending claims, claims 1-5, 7-12, and 33-62 are now in condition for allowance and an indication of such is requested. If, however, there remain any issues which can be addressed by telephone, the Examiner is encouraged to contact the undersigned.

If any extension of time is required, such extension is hereby requested. The Commissioner is hereby authorized to charge payment of any fees associated with this communication, if such fees are due, to Deposit Account No. 19-2090.

Respectfully submitted,

SHELDON & MAK PC

Date: September 19, 2005

By David A. Farah  
David A. Farah, M.D.  
Reg. No. 38,134

Sheldon & Mak  
A Professional Corporation  
225 South Lake Avenue, 9th Floor  
Pasadena, CA 91101  
Tel.: (626) 796-4000  
Fax: (626) 795-6321

**CUSTOMER NO. 23676**